

REMARKS

The present application includes pending claims 50-58 with claim 50 being the only independent claim. Claims 1-49 and 59-66 have been previously cancelled.

In the Final Office Action, claim 57 was rejected under 35 U.S.C. Section 112, first paragraph. Claims 50-56 and 58 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Statutory Invention Registration H1745 to Paraschac in view of U.S. Patent No. 6,126,658 to Baker or, alternatively, such claims were rejected under Section 103(a) as being unpatentable over U.S. Patent 5,688,270 to Yates in view of Baker. Claim 57 was rejected under Section 103(a) as being unpatentable over Paraschac and Baker further combined with one of U.S. Patent Publication 2003/0073991 to Francischelli or U.S. Patent No. 6,096,037 to Mulier. Alternatively, claim 57 was rejected under Section 103(a) as being unpatentable over Yates and Baker further combined with Francischelli or with Mulier.

In response to the Final Office Action, claim 50 has been amended to better define the invention and it is respectfully submitted that amended claim 50 and its respective dependent claims are allowable.

Amended claim 50 is generally directed to a cardiac tissue ablation apparatus. The apparatus comprises first and second jaws which are relatively movable between open and closed positions, respectively, to receive and compress cardiac tissue therebetween. Each jaw has a clamping surface with a width and an elongated electrically conductive member for ablating tissue between the jaws. The conductive members of the jaws are in face-to-face relation and connectible to a bipolar energy power source so as to be of opposite polarity when so connected for providing an

electrical current through a selected tissue ablation area that is located between the jaws. Each conductive member has a tissue contacting portion which has a width that is less than the width of the clamping surface of its associated jaw to contact at least a portion of the selected ablation area.

As recited in amended claim 50, at least one temperature sensor is disposed to sense the temperature of cardiac tissue at a location that is laterally spaced from the tissue contacting portions of the conductive members such that the temperature sensor can detect undesired thermal spread in the compressed tissue that is located outside of the selected ablation area.

Dependent claims 51-58 depend directly from claim 50 and are directed to additional features of the claimed ablation apparatus.

**Baker Does Not Teach or Suggest
The Claimed Temperature Sensor**

The Examiner relies upon the combination of the temperature sensors in Baker with either of the structures disclosed in Paraschac or Yates to reject independent claim 50. However, it is respectfully submitted that such combinations do not teach or suggest the claimed invention of amended claim 50.

Relative to the combination of the cited references with Baker, the Examiner relies upon two temperature sensors 72A, 72B, disposed on the upper jaw 30A, as shown in Figure 5 of Baker. However, such temperature sensors 72A, 72B are disposed, respectively, on upper jaw surfaces 45A, 45B that are directly facing the channeling electrodes 55A, 55B on the lower jaw 30B, with reference to Figure 3B, which shows the lower jaw. Such channeling electrodes "are arranged at any suitable

position between the left and right active bi-polar electrodes" 50A, 50B, which are disposed the upper jaw 30A. (Column 8, lines 2-4, emphasis added).

It is presumed in the Final Office Action that it would have been obvious or routine to laterally space the temperature sensor from the tissue contacting portions of the conductive members in Baker. However, it is respectfully submitted that Baker is directed to solving a different problem and teaches away from such modification so that the subject matter of amended claim 50 would not have been obvious, and would certainly not be routine, to a person of ordinary skill in the art.

Baker is an attempt to address the problem determining when tissue welding is complete and it does this by positioning the temperature sensors to sense the temperature of the tissue being coagulated. As clearly described in Baker, the channeling electrodes conduct electrical current between two active electrodes 50A, 50B. Thus, the location of each temperature sensor in Baker – in facing relation to the currently-carrying channeling electrodes – is disposed to sense the temperature of tissue through which RF electrical energy is conducted by the channeling electrodes – i.e., along the conductive path 135 in Figure 8. (Column 9, lines 42-47). The "individual sensors 72A and 72B [are] carried in a portion of the jaw assembly that contacts the blood vessel section being welded." (Column 8, lines 6-8) (Emphasis added.)

Baker expressly describes that the importance of the location of the temperature sensors to sense the temperature of welded tissue. Such temperature sensors provide the welded tissue temperature to a power controller 70 "to terminate power delivery after the targeted vessel section reaches a predetermined temperature for a sufficient period of time, e.g., from about 1.0 seconds to about 30.0 seconds, to denature proteins

and form a biological glue” to weld the opposed walls of the tubular vessel together (Column 11, lines 57-65). Baker clearly describes use of the temperature sensors to monitor “tissue temperatures ranging between 65 °C and 95 °C” in the tissue to be welded. (Column 12, lines 1-6).

In contrast, the present invention is directed to sensing the temperature of tissue spaced from the ablation zone to monitor for undesirable thermal spread. Thermal spread is not the problem addressed in Baker and the Baker structure is not the solution. Indeed, Baker represents that its structure creates - - little or no thermal spread - - “the bi-polar current [that] flow[s] longitudinally through the vessel provides little or no thermal spread outwardly along the vessel, since the RF current substantially flows along the path directed by the channeling electrodes between the paired ‘active’ electrodes (and not outwardly).” (Column 11, lines 19-23).

So, a fair reading of Baker is that the structure there does not relate to the problem addressed by the present invention, does not provide the solution claimed in the present invention and teaches away from even a recognition of thermal spread as a potential issue.

In summary, in contrast to Baker, the claimed invention provides for at least one temperature sensor that allows for sensing tissue temperature at a location that is laterally spaced from the tissue contacting portions of the conductive members such that the temperature sensor can detect undesired thermal spread in the compressed tissue that is located outside the selected ablation area.

For the above reasons, reconsideration and allowance of claim 50 and its respective dependent claims are respectfully requested.

**The Cited References Do Not Teach or Suggest
The Claimed Apparatus For Other Reasons**

Further, it is respectfully submitted that the cited references do not teach or suggest the claimed invention for other reasons. First, the cited references to Paraschac, Yates and Baker are each directed to apparatuses for coagulation, cutting, welding or sealing of tissue, and not for forming limited lines of ablation.

Each disclosed apparatus teaches a structure that is distinctly different from the claimed ablation apparatus. The claimed ablation apparatus provides for an electrical current through tissue between the jaws only to the extent necessary to form scar tissue to disrupt or break the pathway of an aberrant electrical impulse of the cardiac tissue without causing undue damage to cardiac tissue that may result from cutting, coagulation, sealing or welding such tissue. This is highly different from coagulating, cutting, welding and sealing of tissue and such technologies, are not merely interchangeable, as the Final Office Action seems to suggest.

Further, the cited references teach or suggest a relative wide treatment zone that effectively spans the width of the jaw's clamping surface. For example, Baker teaches offset or staggered electrodes 50A, 50B, 55A, 55B that conduct electrical current across a treatment zone that essentially extends along the entire width of the jaws (Column 9, lines 27-47). This wide treatment zone is consistent with the purpose of Baker, that is, to weld or seal the opposed walls of a tubular vessel or organ together along a substantial length of such vessel, and is inconsistent with the purpose of the claimed ablation apparatus – i.e., to create lines of ablation while avoiding undue damage to cardiac tissue such as would be caused by the cited patent structures. Both Paraschac and Yates also teach a treatment zone that effectively spans the entire width of the jaws

for cauterizing a wide area of tissue prior to cutting to reduce bleeding.

For these reasons, it is respectfully submitted that the subject matter of amended claim 50 would not have been obvious in view of Baker either alone or in combination with any of the other cited references.

Dependent Claim 57 Complies With Section 112, First Paragraph

As described in the prior response, claim 57 is respectfully believed to comply with Section 112, first paragraph, as there is no requirement that all the claimed features must be shown in the same embodiment.

As set forth by the Federal Circuit in JVW Enters. v. Interact Accessories, Inc., 424 F.3d 1324, 1335 (Fed. Cir. 2005), citing Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc), it is improper to "import limitations into claims from examples or embodiments appearing only in a patent's written description, even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.'"

The present application makes clear that it does not intend for the claims and the embodiments to be "coextensive" with a single disclosed embodiment. In the present application, the subject matter of dependent claim 57 – that at least one of the conductive members defines an interior lumen – is disclosed in an embodiment that is described and shown at paragraphs 23 and 97 and in Figure 6 of the published application. Although Figure 6 does not show the temperature sensor of independent claim 50, from which claim 57 depends, the specification makes clear that it does not

intend for the claims and embodiments to be strictly coextensive with any particular disclosed embodiment. For example, Figures 3-6 show alternate constructions of ablating elements for the arrangement of jaws shown schematically in Figure 1 – and other jaw arrangements are disclosed, for example, in the embodiments of Figures 32 and 39, which include a temperature sensor. Also, paragraph 200 of the published application expressly sets forth that “[w]hile the invention has been described in terms of certain preferred embodiments, there is no intent to limit the invention to the same.” (Emphasis added).

Thus, it is respectfully submitted that the claims may include a combination of features from different disclosed embodiments, as clearly contemplated by the specification, and that the rejection of claim 57 under Section 112 should be withdrawn.

Conclusion

For all the above reasons, reconsideration and allowance of claims 50-58 are respectfully requested.

Respectfully submitted,

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